



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/521,461

01/18/2005

Javier Bartoli Orpi

3494-106

2242

6449

7590

06/13/2008

ROTHWELL, FIGG, ERNST & MANBECK, P.C.

1425 K STREET, N.W.

SUITE 800

WASHINGTON, DC 20005

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

06/13/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/521,461	BARTOLI ORPI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-11, 14 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-11, 14, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>na</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1625

Claims 1-11, 14, 19-24 are pending in this application.

Claims 19-22 are drawn to non-elected inventions.

Claims 12-13, 15-18 are cancelled.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Arnolds-Stanton et al., J. Org. Chem. (1991), Vol. 56(1), pp. 151-157.

Arnolds-Stanton et al., disclose compound 13 obtained in a mixture (composition) with similar drugs (others). See page 153, column 1, line 6 to the end of the paragraph. This anticipates the composition of the compound avoided in claim 1 with proviso.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 14, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mu et al., Colloids and Surfaces A: Physiochem. Eng. Aspects (2001), Vol. 181, pp. 303-313.

Applicant claims compounds of formula I and compositions thereof. In preferred embodiments, the compositions comprises additional drug

*Determination of the scope and content of the prior art (MPEP 2141.01)*

Art Unit: 1625

Mu et al., disclose ethyl 2,4-dihydroxybenzoates obtained by Williamson synthesis and used in a mixture with similar compounds. See scheme 1, beginning of paragraphs 3-5 of 2.1. *Materials*, page 305.

*Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)*

The difference between the instant invention and that of Mu et al., is the length of the carbon chain of fluoroalkoxy substituents. These and the instant compounds are adjacent homologs. Also, at position R1, applicant claims alkyl instead of H by Mu et al.

*Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)*

However, H and alkyl are art recognized equivalents. *In re Lincoln*, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960).

When the difference between compounds is the length of a carbon chain such are adjacent homologs. However, adjacent homologs are prima facie obvious. *In re Henze*, 85 USPQ 261 (1950).

Therefore, the instant invention is prima facie obvious from the teaching of Mu et al. One of ordinary skill in the art would have known to replace H with alkyl, and claim adjacent homologs of the compounds of Mu et al., at the time the instant invention was made. The motivation is from knowing that H and alkyl and adjacent homologs are equivalents.

***Response to Argument***

Applicant's arguments filed 3/21/08 have been fully considered but they are not persuasive. Applicant argues that the length of fluoroalkoxy substituents in the instant

Art Unit: 1625

compounds and that of Mu et al., are different. This is not persuasive for reasons set forth above. Applicant further argues that the utilities of the instant compounds and that of Mu et al., are not the same. This is not persuasive because something old or obvious does not become novel upon discovery of a new utility, function or property. *In re Best*, 195 UDPQ 430 (CCPA, 1977). Applicant must show unexpected result through side-by-side comparison with the new utility. Applicant also argues that there is no motivation or suggestion in the prior art to modify the compounds of the prior arts. This argument is foreclosed by the recent decision in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007).

### ***Priority Document***

In response to applicant's unawareness of a need to submit a certified English translation of the foreign document, it must be submitted when requested by the Examiner. See 35 USC 119 9(a)-(d).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1625

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

June 8, 2008